

**Clean copy of the Allowed claims**

1. A system for modeling macrostructural characteristics of a bone comprising:  
a first hierarchical order comprising at least one macroscopic region of the bone,  
a second hierarchical order comprising at least one empirically-derived  
nonhomogeneous second order component representing one or more osteons, trabeculae, or  
lamellae within the macroscopic region, and  
a mechanical property correlated to each of the second order components,  
wherein a mechanical property of the first hierarchical order region is determined  
based on the mechanical properties of the second order components.
2. A system as in claim 1, wherein the bone is compact bone or cancellous bone.
3. A system as in claim 1, wherein the mechanical property is selected from the  
group consisting of tension, compression, shear, bending, torsion, prestress, pinching, and  
cement line slippage.
10. A system as in claim 1, further comprising:  
a third hierarchical order comprising at least one third order component representing  
one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or  
combinations thereof corresponding to one or more regions of the second order components;  
and

a mechanical property correlated to each of the third order components, wherein the mechanical property of each of the second order components is determined based on the mechanical properties of the third order components.

11. A system as in claim 10, wherein the collagen bundles are randomly distributed transversely to an orientation of at least one of the second order components.

12. A system as in claim 1, wherein at least one of the second order components is anisotropic.

13. A system as in claim 1, wherein:  
an external force is applied to the macroscopic region of the bone; and  
a response to the external force is determined based on the mechanical properties of the second order components.

14. A system as in claim 1, wherein the mechanical properties of the second order components are assigned based on a plurality of experimental determinations.

15. A system as in claim 1, further comprising:  
a plurality of subject bones of a specified type;  
wherein a plurality of samples is selected;  
one or more mechanical properties of at least one second order component of each sample is evaluated; and

the evaluations are aggregated to determine the mechanical properties of the second order components.

16. A system as in claim 15, wherein the aggregated evaluations are collected in a database of mechanical properties for the subject bone of the specified type.

17. A system as in claim 15, wherein:

the mechanical properties of the second order components are selected from the group consisting of torsional stiffness, angle-of-twist, and torque;

each of the samples are subjected to monotonic and cyclic torsion tests to produce data on torque and angle-of-twist; and

the mechanical properties of the second order components of the selected bone are determined based on a torque vs. angle-of-twist curve of the samples based on the collected data.

18. A system as in claim 15, wherein:

the mechanical properties of the second order components are selected from tension, compression, shear, bending, and torsion;

each of the samples is subjected to tests to produce data on stress and strain; and

the mechanical properties of the second order components of the selected bone are determined based on a stress-strain curve of the samples based on the data.

19. A system as in claim 10, wherein the mechanical properties of each of the second order components vary in dependence on orientation directions of the third order components.

20. A system as in claim 19, wherein the orientation directions of the third order components are assigned based on experimental determinations.

21. A system as in claim 20, wherein orientation directions of the third order components of the selected bone that is modeled are determined based on the orientation directions of the third order components observed in a subject bone of a specified type.

22. A system as in claim 19, wherein:  
the second order components comprise alternate, extinct, and bright osteons, classified by their appearance in cross section under circularly polarized light;  
the alternate osteons comprise extinct lamellae layered between bright lamellae;  
the extinct osteons comprise extinct lamellae;  
collagen bundles in each of the extinct lamellae are oriented in alternating layers with orientation directions of about  $82^\circ$  and  $-82^\circ$  with respect to the osteon axis; and  
collagen bundles in bright lamellae are oriented in successive layers with orientation directions of about  $-61.5^\circ$ ,  $-41^\circ$ ,  $-20.5^\circ$ ,  $0^\circ$ ,  $20.5^\circ$ ,  $41^\circ$ , and  $61.5^\circ$  with respect to the osteon axis.

23. A system as in claim 10, wherein:

boundary conditions for relative ability to move under loading are assigned to the third order components of the selected bone; and

deformation or fractures are calculated using mechanical properties assigned to the third order components, the force acting on the selected bone, and the boundary conditions of the third order components of the selected bone.

24. A system as in claim 10, wherein a relative amount of the third order components depends on degree of calcification of the second order components.

25. A system as in claim 24, wherein the degree of calcification of the second order components is assigned based on experimental determinations.

26. A system as in claim 22, wherein distribution of alternate osteons, extinct lamellae, and bright lamellae depends on experimental determinations.

27. A system as in claim 1, wherein the second order components comprise voids representing canaliculae, lacunae, or combinations thereof.

28. A method of producing a model of a bone comprising the steps of:

- a) specifying a first order macroscopic region of a selected bone;
- b) dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing an empirically-derived nonhomogeneous second order component comprising one or more osteons, trabeculae, or lamellae;

- c) assigning a mechanical property to each second order component; and
- d) determining a mechanical property of the first order macroscopic region of the selected bone based on the mechanical properties of the second order components.

29. A method of claim 28, further comprising:

dividing each second order component into a finite number of elements, each element representing a third order component comprising one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof; and

assigning a mechanical property to each third order component, wherein the mechanical property of each of the second order components is assigned based on the mechanical properties of the third order components.

30. A method of claim 29, wherein the collagen bundles are randomly distributed transversely to an orientation of at least one of the second order components.

31. A method of claim 28, wherein at least one of the second order components is anisotropic.

32. A method of claim 28, further comprising:

applying an external force to the macroscopic region of the bone; and  
determining a response to the external force based on the mechanical properties of the second order components.

33. A method of claim 28, wherein the mechanical properties of the second order components are assigned based on a plurality of experimental determinations.

34. A method of claim 33, wherein the experimental determinations comprise the steps of:

selecting a plurality of subject bones of a specified type;

selecting a plurality of samples;

evaluating one or more mechanical properties of at least one second order component of each sample; and

aggregating the evaluations.

35. A method of claim 34, wherein the experimental determination further comprises the steps of:

repeating the experimental determination steps for subject bones of different types;

and

compiling a database of representative mechanical properties of each type of subject bone based on the aggregated evaluations.

36. A method of claim 34, wherein the experimental determination further comprises:

performing monotonic and cyclic torsion tests on each of the samples;

collecting data on torque and angle-of-twist of each of the samples;

determining a torque vs. angle-of-twist curve for each of the samples based on the collected data; and

determining the mechanical properties of the second order components of the selected bone based on the torque vs. angle-of-twist curve of the samples.

37. A method of claim 36, wherein the step of determining the mechanical property of the second order components of the selected bone comprises the step of examining the torque vs. angle-of-twist curve to determine if a change of stiffness occurs.

38. A method of claim 34, wherein the mechanical properties are selected from tension, compression, shear, bending, and torsion on each of the samples, the experimental determinations further comprise:

generating data on stress and strain of each of the samples based on testing the selected mechanical properties;

determining a stress-strain curve of the subject bone based on the generated data; and

determining the mechanical properties of the second order components of the selected bone based on the stress-strain curve of the samples.

39. A method of claim 38, wherein the mechanical properties are further selected from the group consisting of Young's modulus, Poisson's ratio, and yield strength.

40. A method of claim 34, wherein the experimental determination further comprises the steps of:



measuring dimensions of samples before and after a step of cutting the subject bone into samples, and before performing a mechanical test on the samples;  
performing a mechanical test on the samples;  
determining a change in the dimensions of each sample; and  
determining a prestress in each sample based on the change in the dimensions of the samples.

41. A method of claim 29, further comprising the step of modifying the mechanical properties of each of the second order components based on orientation directions of the third order components.

42. A method of claim 41, wherein the orientation directions of the third order components are assigned based on experimental determinations.

43. A method of claim 42, wherein the experimental determination further comprises the steps of:  
selecting a subject bone of a specified type;  
observing orientation directions of third order components of the subject bone;  
determining orientation directions of the third order components of the selected bone based on the orientation directions of the third order components of the subject bone.

44. A method of claim 41, wherein:

the second order components comprise alternate, extinct, and bright osteons, classified by their appearance in cross section under circularly polarized light;

the alternate osteons comprise extinct lamellae layered between bright lamellae,

the extinct osteons comprise extinct lamellae, and

wherein the method further comprises the steps of

orienting the collagen bundles in each of the extinct lamellae by alternating layers of collagen bundles with orientation directions of about  $82^\circ$  and  $-82^\circ$  with respect to the osteon axis, and

orienting the collagen bundles in bright lamellae in successive layers with orientation directions in sequence of about  $-61.5^\circ$ ,  $-41^\circ$ ,  $-20.5^\circ$ ,  $0^\circ$ ,  $20.5^\circ$ ,  $41^\circ$ , and  $61.5^\circ$  with respect to the osteon axis.

45. A method of claim 29, further comprising the step of positioning the third order components randomly within a transverse plane of each of the second order components, wherein the transverse plane is positioned transverse to an axis of the corresponding second order component.

46. A method of claim 29, further comprising the steps of:  
assigning a force acting on the selected bone;  
assigning boundary conditions for relative ability to move under loading to the third order components of the selected bone; and

computing deformation or fractures of the selected bone using the mechanical properties assigned to the third order components, the force acting on the selected bone, and the boundary conditions of the third order components of the selected bone.

47. A method of claim 46, further comprising the step of determining fracture lines within the selected bone based on locations of cement lines that are formed between the second order components.

48. A method of claim 46, wherein the boundary conditions of the third order components are assigned based on experimental determinations,

49. A method of claim 46, wherein the boundary conditions of the third order components located at an interface between the second order components are each specified as having freedom of movement under loading.

50. A method of claim 46, wherein the boundary conditions of at least one of the third order components are specified as having freedom of movement under loading.

51. A method of claim 34, wherein the second order sample is an osteon.

52. A method of claim 29, wherein a relative amount of the third order components depends on degree of calcification of the second order components.

53. A method of claim 52, wherein the degree of calcification of the second order components is assigned based on experimental determinations.

54. A method of claim 44, wherein distribution of alternate osteons, extinct lamellae, and bright lamellae depends on experimental determinations.

55. A method of claim 28, wherein the second order components comprise voids representing canaliculae, lacunae, or combinations thereof.

56. A method of claim 27, wherein the macroscopic region is represented by a three-dimensional image, which is divided to provide the finite elements.